Exhibit A

21-2-00711-29 CMP 2 Complaint

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FILED SKAGIT COUNTY CLERK SKAGIT COUNTY, WA

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SUPERIOR COURT OF THE STATE OF WASHINGTON IN AND FOR SKAGIT COUNTY

EILEEN HOLLAND,

Plaintiff,

v.

ACELLA PHARMACEUTICALS, LLC;

SAFEWAY, INC., d/b/a: HAGGEN #3436;

HH LEGACY, INC., d/b/a: HAGGEN FOOD & PHARMACY #15; and

DOE 1 – DOE 25.

Defendants.

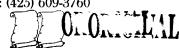
Cause Number:

21-2-00711-29

COMPLAINT

I. INTRODUCTION

- 1. Buyer beware is not the law in the State of Washington.
- 2. To lawfully sell pharmaceutical drugs to consumers in Washington, the drugs must conform to national pharmaceutical standards for strength, quality, and purity.
- 3. For pharmaceutical drugs to conform to compendial standards of strength, quality, and purity, laboratory controls must be scientifically sound and designed to assure that



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components, materials, labeling, and the actual drugs conform to standards.

- 4. Acella Pharmaceuticals, LLC failed to conform to these standards, and sold Acella NP Thyroid® tablets that had excessive amounts of Liothyronine (T3), a man-made form of thyroid hormone.
- 5. A Haggen grocery store in Burlington, Washington purchased the defective Acella NP Thyroid® tablets and re-sold them to Eileen Holland.
- 6. Eileen Holland took the NP THYROID® as ordered by her doctor.
- 7. As directed in the Acella Pharmaceuticals NP Thyroid® Important Safety Information Sheet, Eileen did not stop or change the amount she took, or how often she took it, until eventually told to do so by her medical provider.
- 8. This was unfortunately not until after Eileen had suffered effects of excessive Liothyronine which resulted in her physical and emotional injuries which shall be proved at trial.

II. PARTIES

- 9. Acella Pharmaceuticals, LLC is pharmaceutical company in Forsyth County, Georgia.
- 10. Safeway, Inc. owns the Haggen grocery store in Burlington, Washington (Haggen #3436) where Eileen purchased the defective Acella NP Thyroid® tablets.
- 11. As part of Safeway Inc.'s business it either operates or leases space to other pharmacies at some of its stores; that is the case with Haggen #3436.
- 12. HH Legacy, Inc., does business as Haggen Food & Pharmacy #15, and operates the pharmacy at Haggen #3436.
- 13. Safeway, Inc.; Haggen #3436; HH Legacy, Inc.; and Haggen Food & Pharmacy #15 are

hereinafter collectively referred to as "Safeway."

14. Doe 1 through Doe 25 are persons or business who were involved in the manufacture, oversight, or transaction of defective Acella NP Thyroid® tablets.

III. JURISDICTION AND VENUE

- 15. The Court has personal jurisdiction over all the parties.
- 16. Venue is appropriate in Skagit County Superior Court, where the defective product was sold to Eileen Holland.

IV. FACTS

- 17. Acella Pharmaceuticals, LLC claims that its NP Thyroid® tablets are, "Made with the highest quality standards under cGMP," which is the Current Good Manufacturing Practices for drugs, per Section 21 of the US Code of Federal Regulations Parts 210 and 211.1
- 18. Acella Pharmaceuticals, LLC claims that its NP Thyroid® tablets are subject to Batchto-batch testing to ensure consistent T4 & T3."²
- 19. Regardless of these claims, Acella Pharmaceuticals, LLC failed to conform to Current Good Manufacturing Practices for drugs and sold Acella NP Thyroid® tablets that had excessive amounts of Liothyronine (T3), a man-made form of thyroid hormone.
- 20. The risk and cost of injuries when pharmaceuticals do not conform to Current Good Manufacturing Practices for drugs substantially outweighs the cost for Acella Pharmaceuticals, LLC to make pharmaceuticals that are within standards.

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¹ https://npthyroid.com/about/

² https://npthyroid.com/about/

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- 21. Ordinary consumers would not be aware that their pharmaceutical drugs contain up to 115% of the labeled amount of active ingredient without conducting testing that is cost-prohibitive to the ordinary consumer.
- 22. Consumers do not and would not recognize hormone drugs as safe when they contain up to 115% of the labeled amount of an active ingredient, as was the case with the defective Acella NP Thyroid® tablets.
- 23. Acella's NP Thyroid® tablets did not contain adequate warnings or instructions, including that the drug as actually manufactured may not be FDA approved, nor being sold with a valid biologics license.³
- 24. Acella Pharmaceuticals LLC's sale of its defective NP Thyroid® tablets breached warranties both express and implied.
- 25. On May 22, 2020, the FDA published Acella Pharmaceuticals LLC recall of 30-mg NP Thyroid® tablets based on a warning of super potency and the receipt of at least two adverse events known to be related to the recall.
- 26. Nonetheless, on June 13, 2020, the Safeway defendants sold Eileen 30-mg NP Thyroid® tablets from the recalled lot of defective drugs.
- 27. The defective NP Thyroid® tablets purchased by Eileen were a direct and proximate cause of her injuries that will be proven at trial.
- 28. Doe 1 through Doe 25 have not yet been identified, but were involved in the manufacture, oversight, or transaction of defective Acella NP Thyroid® tablets.

³ See https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/acella-pharmaceuticals-llc-604438-08142020

V. CLAIM FOR DAMAGES UNDER THE WASHINGTON PRODUCT LIABILITY ACT

- 29. Plaintiff Eileen Holland restates and reincorporates each of the preceding paragraphs.
- 30. Defendant Acella Pharmaceuticals, LLC manufactured and supplied a product that was not reasonably safe in construction at the time the product left its control because it did not conform to the manufacturer's express warranty.
- 31. Defendant Acella Pharmaceuticals, LLC supplied a product that was not reasonably safe in construction at the time the product left its control because it did not conform to its design.
- 32. Defendant Acella Pharmaceuticals, LLC supplied a product that was not reasonably safe in construction at the time the product left its control because it did not have adequate warnings
- 33. The defective pharmaceuticals sold to Eileen Holland were the direct and proximate cause of her injuries and damages.
- 34. The collective Safeway defendants were negligent in selling Eileen Holland a recalled drug that was recalled for its super potency.
- 35. None of the collective Safeway defendants warned Eileen Holland that the drugs it sold her had been recalled for super potency.
 - VI. CLAIM FOR DAMAGES UNDER THE CONSUMER PROTECTION ACT
- 36. Plaintiff Eileen Holland restates and reincorporates each of the preceding paragraphs.
- 37. It was deceptive or unfair for Acella Pharmaceuticals, LLC to advertise that its drugs were made under the "highest quality standards under cGMP," when the drugs as

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manufactured did not conform to design.

- 38. It was deceptive and unfair for the Safeway defendants to sell pharmaceutical drugs that were subject to an outstanding drug recall without notifying the buyer before purchase.
- 39. The deceptive and unfair acts of Acella Pharmaceuticals, LLC and the Safeway defendants injured Eileen in her property: the money she spent on drugs that had been recalled.
- 40. The deceptive and unfair acts of Acella Pharmaceuticals, LLC and the Safeway defendants caused Eileen's injury because she would not have taken the drugs but for the deceptive and unfair acts of the defendants.

VII. CLAIM FOR DAMAGES FROM NEGLIGENCE

- 41. Plaintiff Eileen Holland restates and reincorporates each of the preceding paragraphs.
- 42. The Safeway defendants were negligent in selling drugs that were subject to FDA recall.
- 43. The Safeway defendants were negligent for failing to tell Eileen that the drugs they were selling her were subject to FDA recall.
- 44. The negligence of the Safeway defendants caused Eileen's injuries and damages because she would not have taken the drugs but for them selling them to her.

VIII. PRAYER FOR RELIEF

- 45. Wherefore, Plaintiff prays for judgment as follows:
- 46. For her economic losses that were caused by the related injuries;
- 47. For her non-economic losses that were caused by the related injuries;
- 48. For attorney fees and costs, as determined by the Court;
- 49. For jury consideration of trebling damages;